K052934

JUN 12 2006

SECTION 5 – 510(k) SUMMARY

Submission Correspondent: Emergo Group, Inc.
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Contact: Mr. Ian Gordon

Submission Sponsor: S.O.R. Internacional, S.A.
Moines, 13-Pol. Ind. C'an Cassablancas
08192 Sant Quirze del Valles (Barcelona) Spain

Date Prepared: October 17, 2005, Revised April 4, 2006

Trade Name: Dermosonic

Common Name: Therapeutic Massager/Ultrasound Diathermy

Classification:

	Regulation #	Product Code
Massager, Therapeutic	890.5660	89-ISA
Diathermy, Ultrasonic	890.5300	90-IMI

Class II device

Description: The Dermosonic unit is housed in an injected plastic cabinet. Control panels at the top of the cabinet incorporate all the elements required to operate the unit and control and view the various treatment parameters. Below the control panels are spaces to hold the various accessories. There are wheels at the bottom so the device can be easily moved from place to place. Technical specifications for primary components of the devices are:

1. Therapeutic Massager: The device incorporates a motor powered vacuum suction modality with a maximum suction power of 820 milli-bars (mbar). The airflow is rated at 3.500 liters per hour. The device has two suction modes: Continuous and Pulsed. In the Continuous Mode, the suction is constant. In the Pulsed Mode, the suction is intermittent. The suction therapy is delivered to the body with three different size application heads to treat different parts of the body which utilize stainless steel ball bearings to allow the heads to be easily moved over the body. The head are

moved over the body in different patterns and directions to achieve varying treatment objectives.

2. Ultrasonic diathermy (US-6000): The device utilizes a 3 MHz ultrasound head. The applicator crystal is made of AL 6063 (a special type of aluminum commonly used in heat sink material and in CPU cooling fans). Ultrasonic energy can be emitted continuously or intermittently with pulses of limited duration. In the pulse mode, the duration of the pulse (or pulse time) varies from 0.5 milliseconds (msec) to 2 msec. The device allows the operator to select any one of four available ultrasonic emission modes.

Intended Use: The indications for use include the following:

a.Therapeutic Massager:
- i. Provides temporary relief of minor muscle aches and pains
- ii. Relieves muscle spasms
- iii. Temporarily improves local blood circulation
- iv. Temporarily reduces the appearance of cellulite

b. Ultrasonic Diathermy:
- i. Relief of pain
- ii. Muscle spasms
- iii. Joint contractures
- iv. NOT for the treatment of malignancies

Predicate Devices: The predicate device referenced in this submission is:

Sybaritic, Inc.
Dermosonic Non- Invasive Subdermal Therapy System
510(k) K024307

Safety and Effectiveness:

Safety and performance testing has been completed on the S.O.R. Internacional, S.A. Dermosonic.

The S.O.R. Internacional, S.A. Dermosonic is identical to the *Sybaritic, Inc. Dermosonic Non-Invasive Subdermal Therapy System,* 510(k) K024307.

There are no differences between the S.O.R. Internacional, S.A. Dermosonic specifications and the predicate device specifications, and therefore no new issues are raised regarding safety and effectiveness.

Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

There are no differences between the S.O.R. Internacional, S.A. Dermosonic specifications and the predicate device specifications, and therefore no new issues are raised regarding safety and effectiveness. There are no differences in the technological characteristics or in the intended use of these devices.

The S.O.R. Internacional, S.A. Dermosonic device is identical to the predicate device, and therefore we have determined this device to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

S.O.R. Internacional, S.A.
c/o Mr. Ian Gordon
Emergo Group, Inc.
2454 McMullen Booth Road, Suite 427
Clearwater, FL 33759

Re: K052934
Trade/Device Name: Dermosonic
Regulation Number: 21 CFR 890.5300(a)
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Codes: IMI, ISA
Dated: April 7, 2006
Received: April 10, 2006

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K052934

Device Name: **Dermosonic**

The indications for use include the following:

a. Therapeutic Massager:
Provides temporary relief of minor muscle aches and pains;
Relieves muscle spasms;
Temporarily improves local blood circulation;
Temporarily reduces the appearance of cellulite.

b. Ultrasonic Diathermy:
Relief of pain;
Muscle spasms;
Joint contractures;
NOT for the treatment of malignancies.

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052934